621 Rose Street
Lincoln, NE 68502 USA
www.mdsps.com
Tel: (402) 476-2811
Fax: (402) 476-7598

MDS
Pharma Services
Institutional Review Board

Frank E. Landis, Jr.
Chairman

O. Robert Hayes, M.D.

John F. Keller, MBA

Glen F. Lau, M.D.

JoAnn Le Baron, R.N.

Sara W. Morrow, Pharm.D.

Richard C. Toren, M.D.

Samuel Van Pelt

Judy E. Carver
Secretary

September 22, 2003

James C. Kisicki, M.D.
MDS Pharma Services
621 Rose Street
Lincoln, NE 68502

RE: **Philip Morris**
A Randomized, Controlled Study Comparing the Short Term Exposure to Smoke Constituents of the EHCSS K 6 to Marlboro Lights and Marlboro Ultra Lights in Adult Smokers During Controlled Smoking, Protocol No. 466-06, Protocol dated May 1, 2003, Protocol Amendment 1 dated June 9, 2003, Investigator's Brochure, Electrically Heated Cigarette Smoking System (EHCSS – Series K), Edition 1.0 dated April 10, 2003

Dear Dr. Kisicki:

On September 22, 2003, Sara W. Morrow, a member of the MDS Pharma Services Institutional Review Board and designated to do expedited reviews, acknowledged receipt of two notes-to-file dated September 14 and September 15, 2003. Copies of the documents are enclosed for the convenience of your review.

Philip Morris, USA, the sponsor of this study, has been notified of this action by receipt of a signed copy of this letter. There were no revisions necessary to the informed consent form.

The Board is fully aware of the regulations governing institutional review boards (Part 56 of Title 21 of the Code of Federal Regulations) and believes that its operations are in compliance with those regulations.

Sincerely,

Judy E. Carver, Secretary
Institutional Review Board

Enclosure

c: Hanes-Juergen Roethig, M.D., Ph.D., FCP, FFPM
Philip Morris USA
615 Maury Street
Richmond, VA 23224

AA02981

Source: https://www.industrydocuments.ucsf.edu/docs/pypx0001